(c) Railways construct Road Over/Under Bridges (ROB/RUB) in lieu of existing level crossings on cost sharing basis if the traffic density is more than one lakh TVUs. (TVU—A unit obtained by multiplying the number of trains with the number of road vehicles passing over the level crossing in 24 hours), otherwise considers on deposit basis. Proposals in both cases have to be sponsored by State Govt. No proposal has been received from the State Govt, for ROB at Rangapara.

SHRI SILVIUS CONDPAN: Sir, in response to the reply given by the hon. Minister to part (a), (b) and (c) of my question, I would like to know from the hon. Minister a clarification. He has said that density of traffic at the level-crossings is not more, therefore, ROB is not possible now. Sir, it is not only lakhs of people using this level crossing but also it is being used by army vehicles. This is a cantonment area. In view of this, may I know from the hon. Minister that till all these formalities are completed whether he would advice his Railway Department not to block this level crossing on the pickets by shunting. They do shunting. As a result, trains are blocking for hours together. This is one of the problems. That is why I put **this** question. May I know from the hon. Minister whether he would take some action?

SHRI R. VELU: Sir, it is for the safety of the people we are closing the gates, during shunting and to keep all the trains moving. In the entire day, we are closing only for few hours in intervals of half-an-hour, 15 minutes, 20 minutes like that. I will get it examined how this can be minimised.

MR. CHAIRMAN: Question Hour is over.

WRITTEN ANSWERS TO STARRED QUESTIONS

Clinical trials of neseritide

*425. SHRI P.R. RAJAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether permission has been granted during the last two years, by the Drug Controller General of India to conduct clinical trials on a drug called Neseritide (Natrecor), manufactured by Johnson and Johnson, USA;

(b) if so, the details thereof;

(c) whether the Drug Controller General of India sought certain clarifications and expressed reservations for granting permission for clinical trials to another agency which applied for clinical trial of same drug;

(d) if so, whether above clarifications were resolved before granting permission for doing clinical trials; and

(e) whether Government are aware that South Africa denied clinical trials of the above drug?

THE MINISTER OF HEALTH AND FAMILY WELFARE (DR. ANBUMANI RAM DOSS): (a) to (e) The permission was granted to a Clinical Research Organisation (CRO) to conduct a Phase III clinical Trial on Neseritide (Natrecor), manufactured by Johnson and Johnson, USA. Neseritide is already marketed in USA since 2001. It is also marketed in Israel, Switzerland and Argentina.

The permission to conduct the trial was granted after seeking necessary clarifications and submission of reports by the firm. The firm submitted the report where a panel of Expert Cardiologists in USA had recommended the trial. No other company was refused permission to conduct clinical trials with the drug. The sponsors had themselves changed the CRO and notified this Ministry. The firm had submitted copies of approvals of the trial from Canada, Latin America and USA. According to the information provided by the firm recently, the trial has been approved by Medicine Control Council, South Africa and recruitment of patients is ongoing in South Africa.

Environmental clearance to Dholera Port

*426. SHRI SURYAKANTBHAI ACHARYA:

SHRI KANJIBHAI PATEL:

Will the Minister of ENVIRONMENT AND FORESTS be pleased to state:

(a) whether it is a fact that a proposal for environmental clearance in respect of Dholera Port **has** been received by the Central Government from the State Government of Gujarat;